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(to be used for all correspondence after initial filing)

Application Number	09/200,055
Filing Date	November 25, 1998
First Named Inventor	Garibaldi et al.
Group Art Unit	3763
Examiner Name	Michael M. Thompson
Attorney Docket Number	5236-000157

Total Number of Pages in This Submission 28

## ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form  <input type="checkbox"/> Fee Attached  <input type="checkbox"/> Amendment / Response  <input type="checkbox"/> After Final  <input type="checkbox"/> Affidavits/declaration(s)  <input type="checkbox"/> Extension of Time Request  <input type="checkbox"/> Express Abandonment Request  <input type="checkbox"/> Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s)  <input type="checkbox"/> Response to Missing Parts/ Incomplete Application  <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application)  <input type="checkbox"/> Drawing(s)  <input type="checkbox"/> Licensing-related Papers  <input type="checkbox"/> Petition  <input type="checkbox"/> Petition to Convert to a Provisional Application  <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address  <input type="checkbox"/> Terminal Disclaimer  <input type="checkbox"/> Request for Refund  <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group  <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input checked="" type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)  <input type="checkbox"/> Proprietary Information  <input type="checkbox"/> Status Letter  <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):  <b>Postcard</b> <b>2 Additional Copies of Reply Brief</b>
<b>Remarks</b>		

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Elizabeth D. Odell 39,532
Signature	
Date	January 6, 2003

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: Garibaldi et al.

Serial No.: 09/200,055

Filed: November 25, 1998

For: METHOD OF AND APPARATUS FOR NAVIGATING  
MEDICAL DEVICES IN BODY LUMENS BY A GUIDE WIRE  
WITH A MAGNETIC TIP

Examiner: Michael M. Thompson

Group Art Unit: 3763

Commissioner for Patents  
Washington, D.C. 20321

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APPLICANTS' REPLY BRIEF

Pursuant to 37 C.F.R. § 1.193 (b)(1), Applicants submit their Reply Brief, as follows.

Applicants have described, drawn and claimed a flexible magnetic material that is not anticipated by or obvious over Anderson, U.S. Patent No. 4,244,362.

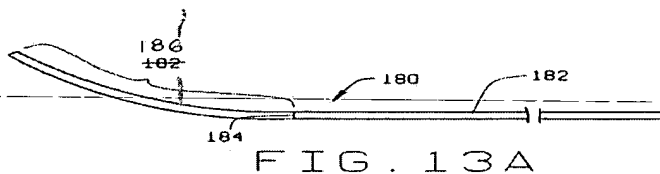
~~Claims 3, 9, 15, 19, 26 and 30 are rejected as anticipated by or obvious over Anderson, U.S. Patent No. 4,244,362. Claims 3, 9 and 26 (and claim 30, which depends from claim 26) recite a flexible magnetic material forming a distal end section of the guide wire. Claim 15 (and claim 19, which depends from claim 15) recite a distal section of the guide wire being made from a flexible magnetic material. The foregoing claims are clearly supported in the specification, in which is described, for example, an embodiment (shown in Figs. 13 and 13A) as follows:~~

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Instead of the single magnet on the distal end of the wire, or a plurality of magnets on the distal end portion of the wire, the distal end portion 186 of guide wire 180 is made from a flexible magnetic material. The distal end portion 186 is preferably about 0.25 mm (0.01 inches) in diameter, and about 1 cm (0.4 inches) long. The distal end portion can be made of a permeable magnetic material such as a steel or a magnetic stainless steel wire, or a steel or a magnetic stainless steel braid. As shown in Fig. 13a, upon the application of a magnetic field, the distal end portion 186 of the guide wire 180 assumes a particular orientation dictated by the field. Thus by controlling the applied magnetic field, the orientation and/or shape of the distal portion 186 of the guide wire 180 can be controlled, facilitating the navigation through the body lumen.

Specification, page 13, lines 35-36, page 14, lines 1-16.

Figs. 13 and 13A were amended, in Applicants' Amendment and Response A filed June 26, 2000, to show the reference number 186, but may have been reproduced in Applicants' Brief on Appeal in unamended form. Figs. 13 and 13A are reproduced below in their amended form.



(Figs. 13 and 13A from Application Serial No. 09/200,055)

The Examiner concedes (in his Answer at page 4, lines 14-16) that one must turn to Applicants' specification for a reasonable determination of what Applicants consider to be a flexible magnetic material, yet the Examiner

apparently ignores the foregoing excerpt from the specification. The Examiner incorrectly asserts that Applicants cite neodymium-iron-boron or samarium cobalt as suitable materials that Applicants consider to be flexible magnetic materials (Answer at page 4, lines 16-18). Nowhere in the specification is there such a citation. To the contrary, the specification cites that the flexible distal end portion can be made of a permeable magnetic material such as a steel or a magnetic stainless steel wire, or a steel or a magnetic stainless steel braid.

During patent examination, the pending claims must be given the broadest reasonable interpretation consistent with the specification. In re Morris, 44 USPQ 2d 1023, 1027 (Fed. Cir. 1997); MPEP 2173.05(a). Unless a term used in the claims is given a special meaning in the description, generally no term may be given a meaning repugnant to the usual meaning of the term. In re Hill, 73 USPQ 462 (CCPA 1947; MPEP 2173.05(a). The "flexible magnetic material" cited in Applicants' specification and claims is sufficiently flexible to allow it to flex in response to an applied magnetic field. There is no special meaning given to the word "flexible" in the present specification. Therefore the present claims should be construed in accordance with the usual meaning of the word "flexible". The Examiner concedes (in his Answer at page 6, lines 9-10) that when one thinks of the common interpretation of "flexible", one might think of a rubber material. The Examiner, however, takes the position that the term "flexible" is to be defined relative to a modulus of elasticity for neodymium-iron-boron or samarium cobalt, and dismisses the foregoing specification reference to stainless steel braid as not germane to the issues at hand (Answer at page 9, lines 6-8).

To interpret the word "flexible" as urged by the Examiner clearly would subvert the ordinary meaning of the word. By the Examiner's logic, the flexible magnetic material of Applicants' claims would exhibit the same "flexibility" as permanent magnets, effectively eliminating the word from the claim. The Examiner's interpretation of the word "flexible" is explicitly contradicted in the specification and drawings. For example, the flexing behavior of the guide wire distal end portion 186 as shown in Fig. 13A makes it clear that the word "flexible" as used in the claims and specification is to be given its usual meaning.

The Examiner also states that Applicants' claims might be construed to include a grouping of magnetic material that is collectively flexible, and that such a grouping is taught by Anderson. It simply is not accurate to refer to the magnets of Anderson as "flexible magnetic material". As discussed in Applicants' Brief on Appeal (at pages 6-7), the magnetic characteristics of a flexible magnetic material are markedly different from the bipolar, closely packed lineup of magnets taught by Anderson.

Applicants respectfully traverse the Examiner's statement (Answer at page 8, lines 22-24) that Applicants have factually misstated the teaching of Anderson with respect to lateral movement of the stylet distal portion. The Examiner is correct to the extent that Anderson teaches the use of an external magnet to attract the tip (i.e. magnet 61) of the distal portion, which can cause lateral movement of the end portion as illustrated in Anderson. Attracting the tip, however, is significantly different from attracting a lateral point of the stylus end portion to cause lateral movement. Applicants maintain that if it were possible to magnetically attract lateral points of the stylus of Anderson, the resulting movement of the stylus could prevent the tip from entering the trachea. Anderson teaches away from magnetically attracting magnets 60 of the end portion in directions other than in single-file behind the tip magnet 61. Anderson thus does not anticipate Applicants' flexible magnetic material, which can be magnetically attracted at a plurality of points and in a plurality of directions.

In conclusion, it is clear that the Examiner has mistakenly construed Applicants' use of the term "flexible magnetic material" in the specification, drawings and claims. The Examiner unduly limits construction of the word "flexible" to a meaning repugnant to the usual meaning of the term. The Examiner then concludes that Anderson inherently teaches the same degree of "flexibility". The Examiner has provided neither objective evidence nor cogent technical reasoning to support the conclusion of inherency; MPEP 2112. Applicants respectfully submit that the Examiner's position is contradicted by the specification, the drawings and the usual construction of the word "flexible".

Applicants' plurality of magnets on the distal end section of the guide wire in spaced apart relation is not anticipated by or obvious over Anderson, U.S. Patent No. 4,244,362.

Claims 16, 27, 34-37, 41 and 42 are rejected as anticipated by or obvious over Anderson, U.S. Patent No. 4,244,362. Claim 16 (and claim 41, which is dependent on claim 16) and claim 34 (and claims 35-37, which are dependent on claim 34) recite methods that include inserting a guide wire having a magnetic distal tip comprising a plurality of magnets secured on the distal end section of the guide wire in spaced apart relation. Claim 27 and claim 42 (which is dependent on claim 27) recite a guide wire having a magnetic distal tip that comprises a plurality of magnets on the distal end section of the guide wire in spaced apart relation.

The Examiner maintains that Anderson teaches a plurality of magnets in a spaced apart relationship, and points to Figure 11 of Anderson in support of his position. It nevertheless is clear from Figure 10 of Anderson that the magnets of Anderson are not secured on the distal end of a guide wire in spaced apart relation. The magnets of Anderson are secured in a relationship in which they always contact one another. Specifically, the magnets 60 have a diameter smaller than the diameter of the encasing spring 55 (Anderson, column 6, lines 59-66) and thus are free to cling to one another while the spring 55 is straight. The magnets 60 are not secured on, but encased in the distal end of the spring 55, and are secured in full lateral contact with one another by the magnetic force exerted between them. It is only when the stylet is bent that the magnets of Anderson may be caused to assume a position that the Examiner incorrectly maintains is a "spaced apart relationship". Even when they interact as shown in Figure 11, the magnets do not totally part from one another, but may partially separate (Anderson, column 7, lines 21-23), and only for so long as the spring 55 is bent.

Unlike the magnets of Anderson, which always touch one another, Applicants' claimed magnets are "spaced apart". To "space" means "to organize

or arrange with spaces between; to separate or keep apart". The word "apart" means "at a distance in place, position or time; away from another or others; in or into parts or pieces; one from another; aside or in reserve, as for a separate use or purpose; as a distinct item or entity; ..." The American Heritage® Dictionary of the English Language, Fourth Edition, Houghton Mifflin Company (2000).

Because the magnets recited in the claims are in spaced apart relation, they have magnetic and functional characteristics significantly different from those of the mutually touching magnets of Anderson, as discussed in Applicants' Brief on Appeal (at pages 8-9). Claims 16, 27, 34-37, 41 and 42 recite a structure that is not taught by Anderson. Because the magnets of Anderson are always touching one another, it is incorrect to describe them as being "in spaced apart relation".

Applicants' claims 3, 9, 15, 19, 26 and 30 are patentably distinct and not merely obvious variations of the invention set forth in claims 1-18 of Werp et al., U.S. Patent No. 5,931,818.

The Examiner has withdrawn claims 16, 34-37 and 41- 42 from the instant rejection. Claim 42 is dependent on claim 27, the status of which is unclear with respect to the instant rejection. Since claims 27 and 42 stand together for purposes of this appeal, Applicants assume that claim 27 also has been withdrawn from the instant rejection.

As discussed above, claims 3, 9 and 26 (and claim 30, which depends from claim 26) recite a flexible magnetic material forming a distal end section of the guide wire. Claim 15 (and claim 19, which depends from claim 15) recite a distal section of the guide wire being made from a flexible magnetic material.

The Examiner asserts (in his Answer at page 7, lines 19-21) that Applicants' arguments are factually incorrect, but he does not specify which facts are at issue that may be relevant to the instant double-patenting rejection. The Examiner also asserts (in his Answer at page 8, lines 14-20) that Werp et al. both teach and suggest the use of a flexible magnetic material. In taking this position,

the Examiner again relies on an apparent misreading of Applicants' specification. As discussed above, Applicant's application does not teach that neodymium-iron boron is a suitable flexible magnetic material. The Examiner's stated position that the magnet of Werp et al. is clearly flexible is clearly wrong. Werp et al. do not describe a flexible magnet, nor can Applicants' specification be accurately construed to infer that the magnet of Werp et al. is "flexible" in a way that anticipates the present claims. As previously discussed, the word "flexible" is to be accorded its usual meaning in relation to Applicants' specification and claims. As discussed above, Applicants' specification and claims recite a flexible magnetic material, which is neither taught nor suggested by Werp et al.

Applicants traverse Examiner's arguments that have not yet been addressed.

The Examiner (beginning in his Answer at page 8, line 21) addresses several assertions made by Applicants in their Brief on Appeal. Several of the Examiner's arguments have been discussed above, and Applicants shall now address those arguments remaining. In response to the Examiner's argument (page 9, lines 6-8) that Applicants have not claimed a flexible stainless steel braid, Applicants submit that they have claimed a flexible magnetic material, which includes flexible stainless steel braid.

The Examiner asserts (at page 9, lines 8-9) that Applicants claim that the distal portion of the guide wire can be moved in any direction, and that Anderson teaches similarly. The Examiner has construed Applicants' statement too narrowly. Applicants assert that the distal portion of the guide wire can be magnetically attracted in a plurality of directions, thus allowing for movement and shaping of the distal portion in a variety of ways. It is clear that the strictly bipolar magnetization and close, touching arrangement of the Anderson magnets do not allow the Anderson stylet to be moved magnetically in any direction other than as defined by the stylet tip. It can be seen that the individual magnets of Anderson are not configured to respond to a magnetic field except through the end magnet



61. In contrast, a flexible magnetic material can be attracted, moved and shaped in a plurality of ways.

The Examiner also asserts (in his Answer at page 9, lines 9-12) that, given the Examiner's interpretation of the "flexibility" of Applicants' material, Anderson can be seen to teach a flexibility that enables the distal end of a guide wire to capture and recover objects. This assertion certainly is not supported by the Anderson disclosure. It is obvious that this assertion is supportable only by the Examiner's incorrect construction of Applicants' specification and his redefinition of the term "flexible".

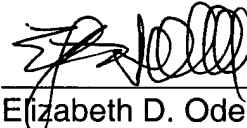
The Examiner asserts (in his Answer at page 9, lines 13-19) that Applicants are factually incorrect in stating that the limitations of claims 26, 27, and 35-37 have not been met. The Examiner argues that it is inherent in Anderson for a user of the stylet to have placed it into the lumen of the medical device before the stylet is extended through the distal end of the device. It is not inherent in Anderson, however, for the user to insert the stylet into a medical device having a closed distal end. Claims 26, 27 and 34 (and claims 35-37, which are dependent on claim 34) recite a medical device having a lumen extending substantially to the distal end of the device. In contrast, the lumen in the tube of Anderson extends through the distal end.

Anderson also does not disclose or suggest a proximal end of the stylet that is sufficiently stiff to advance the medical device, as recited in claims 26 and 27, nor does Anderson disclose or suggest applying a magnetic field to orient the magnetic tip of the guide wire inside the lumen of the medical device so that the distal end of the medical device is oriented in the desired direction of travel, as recited in claim 34. In contrast, Anderson discloses a stylet that is directed through the distal end of the medical device and then is magnetically oriented in the desired direction of travel (Figs. 5-7; Figs. 8-9). The medical device subsequently is guided along the stylet (Anderson, column 6, lines 50-51).

### Conclusion

The Examiner has skewed the definition of "flexible" so as to be applicable, for example, to a permanent magnet, which is certainly inflexible in the usual sense of the word. Having redefined "flexible", the Examiner then applies the teachings of Anderson in ways that may follow logically from the Examiner's redefinition, but that approach absurdity when considered in light of the normal definition of "flexible". Applicants' specification and claims are not so indefinite as to call for the approach taken by the Examiner. Applicants' claims are supported by the specification and are novel when their words are accorded their usual meanings. The rejections of claims 3, 9, 15, 16, 19, 26, 27, 30, 34-37, 41 and 42 therefore should be reversed.

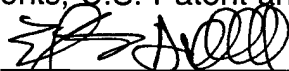
Respectfully submitted,



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### CERTIFICATE OF MAILING

I certify that on January 6, 2003, APPLICANTS' REPLY BRIEF (in triplicate) was sent by U.S. Postal Service Express Mail to the U.S. Patent and Trademark Office, address to Commissioner for Patents, U.S. Patent and Trademark Office, Washington, D.C. 20231.



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